UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 26, 2013

MEMORANDUM

Subject: Human Health and Ecological Risk Assessment of the Proposed Registration of the New Active Ingredient Ammonium Carbamate as Spectrum XD 1878 to Produce Monochloroamine for Pulp and Paper Mills and Recirculating Cooling Systems

PC Code(s): 000374	DP Barcode(s)/No(s): 412666
Decision No.: 474381	Registration Number (s): 74655-GU
Petition No(s).: NA	Regulatory Action: Product Registration – Section 3
Risk Assess Type: Single Chemical	Case No(s): NA
TXR No.: NA	CAS No(s): 1111-78-0
MRID No(s).: NA	40 CFR: NA

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The Agency has assessed the human health and ecological risks for the proposed registration of ammonium carbamate as a new active ingredient to produce monochloramine to treat pulp and paper mills and re-circulating cooling water systems. There are no risks of concern for either ammonium carbamate or monochloroamine provided that the label instructions are followed.

BACKGROUND

Ashland Inc. has requested to register Spectrum XD1878 (EPA Reg. No 74655-GU) containing 19.5% ammonium carbamate. This product is proposed for use as a slimicide in paper and paperboard water systems and in re-circulating cooling water systems. This product is to be mixed in situ (on site) with sodium hypochlorite to produce chloramine. The application rate is expressed as a residual in terms of total chlorine and is 0.5 to 10 ppm for paper mills and 0.3 to 5.0 ppm for re-circulating cooling water systems.

HUMAN HEALTH HAZARD CHARACTERIZATION

Acute Toxicity

Ammonium carbamate is of low acute oral toxicity (i.e. Toxicity Category III) based on an LD_{50} of 1080 mg/kg in the rat and is of low dermal toxicity (Toxicity Category IV) based on a LD_{50} of >5000 mg/kg in the rat. It is a severe eye irritant (Toxicity Category I) based on the primary eye irritation study in rabbits and it is not a dermal irritant (Toxicity Category IV) based on the primary dermal irritation study in rabbits. It is not a dermal sensitizer based on the local lymph node assay in mice. The requirement for the acute inhalation study was waived.

Repeat Dose Toxicity

Ammonium carbamate is of low toxicity. Ammonium carbamate is in equilibrium with ammonium bicarbonate and ammonium carbonate in aqueous solution at neutral pH. Ammonium carbonate and bicarbonate are used in baking powder formulations, cooling baths and smelling salts.

HUMAN EXPOSURE AND RISK ASSESSMENT

Occupational Exposures

The registrant's proposed label and supporting information in MRID 49042918 indicate that the risks for worker exposure are not of concern. As indicated on the proposed label, ammonium carbamate will be mixed with sodium hypochlorite in a specially designed reactor to produce monochloramine onsite. The supporting information indicates that ammonium carbamate is transferred from the shipping container to the reactor via a closed system and therefore worker exposure to ammonium carbamate is not anticipated. It is also understood that the reaction will be optimized to produce monochloramine, which is non-volatile, while preventing the production of unwanted byproducts, such as trichloroamine, which is volatile and toxic.

Residential Exposure

No residential exposure scenarios are associated with the proposed uses of ammonium carbamate.

Dietary and Drinking Water Exposures

No dietary (food) risks are expected to be associated with the proposed uses. The only potentially toxic compound resulting in the water system from the uses of ammonium carbamate is monochloramine, however, any monochloramine not consumed in the water system is expected to degrade under the high temperature conditions of the paper drying process (110° C) and it is not expected to remain in the paper to migrate to food.

No drinking water risks are expected from the proposed uses of ammonium carbamate. Very low levels of monochloramine may survive to the point of discharge. EPA has established a maximum residual disinfectant level (MRDL) of 4.0 ppm for chlorine (which includes chlorine from monochloramine) and water utilities are required to maintain chlorine at or below this MRDL. Because the maximum application rates (10 ppm for paper mills and 5 ppm for recirculating cooling systems) are only marginally above the MRDL and the fact that most of the monochloroamine will be consumed during the treatment process, it is highly unlikely that drinking water exposures to monochloramine will result in risks of concern.

Aggregate Exposures

As there are no dietary (food or drinking water) or residential exposures associated with the proposed uses of ammonium carbamate, there is no need to estimate aggregate exposures based on the proposed uses.

CUMULATIVE RISK

EPA does not have, at this time, available data to determine whether ammonium carbamate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. This chemical is of low systemic toxicity and no adverse effects on human health are expected, other than eye irritation from acute exposure. For the purposes of this Section 3 registration action; therefore, EPA has assumed that ammonium carbamate does not have a common mechanism of toxicity with other substances largely because it elicits no adverse effects in mammals.

ENVIRONMENTAL FATE AND EXPOSURE

Ammonium Carbamate

Ammonium carbamate is highly water soluble, and as soon as it is dissolved into water it converts into ammonium carbonate, which is like other ammonium salts: water soluble, and the chemistry and fate of such chemicals is due to ammonia/ammonium ions. Routine ammonium carbamate (or ammonium carbonate) releases or discharges to the environment are not anticipated for the proposed uses because the product is mixed with sodium hypochlorite a closed system to produce monochloramine. Releases or discharges would only occur as a result of a system failure or spill and such situations are covered by the precautionary statements on the product label.

Monochloroamine

Monochloramine exposures to the environment are not of concern for the proposed pulp and paper mill use because of the physical/chemical characteristics of monochloroamine (short hydrolytic half life and readily biodegradable) and the characteristic of the paper mill process (high organic content of paper mill waste water and the holding time of wastes prior to any discharge to surface water).

Monochloramine exposures are not of concern for the proposed recirculating cooling water uses because the proposed label contains the statement that residual monochloroamine must be neutralized so that discharges not exceed the EPA Office of Water Ambient Water Quality Criteria of 2 ppb for fresh water and 3 ppb for salt water.

Summary of Environmental Fate and Exposure

As discussed above, no exposure is likely due to ammonium ions, or carbamate, or monochloramine in the environmental media.

ECOLOGICAL EFFECTS AND RISK ASSESSMENT

As discussed above, ammonium carbamate is handled in a closed system and exposures are only anticipated in the event of a system failure or spill. In addition, discharges of monochloramine are expected be minimal based on the fate of monochloroamine in paper mill systems and on the label discharge requirements for recirculating cooling water systems. Therefore, the risks to non-target organisms are not of concern.

ENDOCRINE DISRUPTION

As required under FFDCA section 408(p), EPA has developed the Endocrine Disrupter Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain postapplication agricultural scenarios. This list should not be construed as a list of known or likely endocrine disrupters.

Ammonium carbamate is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.